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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,329	07/08/2003	Hiromasa Hashimoto	223488	9373

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EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 08/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/615,329	HASHIMOTO ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-110* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-110* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/939,374.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Requirement for Restriction
~and~
Election of Species

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 42-93, drawn to fused ring compounds, classified in numerous classes and subclasses, depending on the identities of the variables in the core fused ring system.

II. Claims 1-41, 94-101 and 103-110, drawn to "therapeutic agents" for hepatitis C, pharmaceutical compositions, methods of inhibiting hepatitis C polymerase and methods of treating hepatitis C, comprising (administering) the compounds as are set forth in Group I above, classified in class 514, in numerous and divers subclasses, depending on the chemical identity of the fused ring compound serving as the therapeutic agent.

III. Claim 102, drawn to two thiazole compounds unrelated to the compounds of Group I as set forth above, in class/subclass 548/179

Inventions I and II are related as product and process of use and a sub-product specially adapted for that use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case hepatitis C is treated with materially different compounds than those

set forth in Group I herein. Ribavarin and interferon are commonly used to treat hepatitis C virus infection.

The search required for determination of the patentability of Group II subject matter will be of a different scope than the search required for determination of the patentability of Group I subject matter, for at least the reason that the examiner will need to consider the state of the art in treatment of hepatitis C infection in order to determine whether the first paragraph of 35 U.S.C. 112 is satisfied with respect to the instant claims. In order to make the decision as to whether the methods as claimed are enabled by the disclosure, the examiner must consider the knowledge possessed by one of ordinary skill in the art to which the claimed subject matter pertains, which in the case of Group II subject matter is medicine. If treatment of hepatitis C with drugs inhibiting the virus' polymerase is state of the art, then the methods likely will be deemed enabled. Such a "state of the art" search is not required when surveying the literature for simple disclosures of chemical compounds, because the synthesis examples given in the references are enabling in and of themselves.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are completely different types of compound.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized

divergent subject matter and separate classification restriction for examination purposes as indicated is proper.

NOTE:

The phrase "therapeutic agent" is ambiguous. It is not defined in the specification. A composition, such as a pharmaceutical composition, which comprises the compound specified in the claims and some carrier material could be described, or a compound *per se* might be described by the phrase. Claims specifying "therapeutic agents" and claims specifying "fused ring compounds" could be objected to on grounds that they are duplicate claims.

This Requirement is Further Set Forth as Follows:

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Claims 1 and 42 (the independent claims) read on vast numbers of chemical compounds which are patentably distinct from one another. The fused ring core of the compounds is variable to many different ring systems, all of which are not obvious over one another. A reference rendering one such ring system unpatentable would not necessarily be such a reference for other embodiments within the same claim. In addition to the variable core, the substituent groups, such as the "Cy" and "A" rings are variable to the point of providing for patentably distinct classes of compound. A complete, exhaustive search of the claims of one of the Restriction Groups set forth hereinabove would place an undue burden on the examiner.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election. Applicants' failure to supply the list of claims readable on the elected species will be taken as an incomplete response to this Requirement.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141, the search will not be unnecessarily broadened, however. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This Requirement is Subject to the Following Condition:

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not

commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species and invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Monday to Friday from 5:45am to 2:15pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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